

Section 5 510(k) Summary per 21 CFR §807.92 (c)

Submitter's Name and Address	Boston Scientific Corporation Electrophysiology 150 Baytech Drive San Jose, CA 95134
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Date Prepared	March 21, 2014
Trade Name	Constellation® Multiple Electrode Recording and Pacing Catheter
Common Name	Catheter, Intracardiac, High Density Array
Classification Name	Catheter, Intracardiac, High Density Array (Product Code MTD) has been classified as Class II per 21 CFR 870.1220
Predicate Device	The Constellation Catheter Multiple Electrode Recording and Pacing Catheter is substantially equivalent in design and intended use to the same device legally marketed under K983171, K992777, K000277, K003782 and K021232 and Johnson & Johnson/Biosense-Webster Flower High-Density Mapping Catheter/ PENTARAY™ High-Density Mapping Catheter legally marketed under K050217.

Description of Device

The Boston Scientific Constellation® Multiple Electrode Recording and Pacing Catheter (Constellation Catheter) is a sterile, single use advanced heart mapping diagnostic device designed to detect electrical potentials from the endocardial surfaces of the heart and may also be used to deliver externally generated pacing stimuli. The distal expandable 'basket' assembly contains an array of 32 or 64 electrodes mounted along eight resilient support structures called 'splines.' Several configurations are available, including unipolar (electrodes evenly spaced), bipolar (electrodes evenly distributed into pairs), and lower density arrays. The product is available in 31, 38, 48, 60, and 75mm basket sizes.

Intended Use/Indications for Use

For use in right and left atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli.

Device Technological Characteristics and Comparison to Predicate Device

The Constellation Catheter indicated for use in left atrial electrophysiology procedures is the same device indicated for use in right atrial procedures. Design, principle of operation, and materials are identical to the Constellation Catheter cleared under K983171, K992777, K000277, K003782 and K021232 and equivalent to the Johnson & Johnson/Biosense-Webster Flower High-Density Mapping Catheter/ PENTARAY™ High-Density Mapping Catheter legally marketed under K050217.

Expanding the indication of the Constellation Catheter does not involve incorporation of new design features, which are identical to the predicate Constellation Catheter. In support of substantial equivalence, Boston Scientific has compared and evaluated technological characteristics of the Johnson & Johnson/ Biosense-Webster Flower/PENTARAY High-Density Mapping Catheter to the Constellation Catheter. The Constellation Catheter is unique only in its geometrical configuration of splines and electrodes. Otherwise, the devices are similar in all other technical aspects.

Non-Clinical Performance Data

Device design specifications are identical for both the predicate and subject Constellation Catheter. Therefore the non-clinical testing for the Constellation Catheter that was submitted in previous submissions (K983171, K992777, K000277, K003782, and K021232) remains relevant.

**Clinical
Performance
Data**

Safety and effectiveness of the Constellation Catheter with expanded indications for use to include the left atrial electrophysiology procedures is based on cumulative animal and human data. Human clinical data include safety and effectiveness data from the original Constellation Catheter IDE (G940612) and safety data for use in the left atrium as evidenced from published medical literature, and in particular, from the CONFIRM [Conventional Ablation With or Without FIRM (Focal Impulse and Rotor Modulation)] study reported by Narayan et al (2012). In the CONFIRM study, the Constellation Catheter was advanced via an 8.5 F sheath to map the left atrium in 92 patients. There were no strokes or TIAs (transient ischemic attack) reported nor any unanticipated complications related to cardiac catheterization and/or ablation.

Conclusion

The Constellation Catheter with expanded indications for use to include left atrial electrophysiology procedures is substantially equivalent to the predicate Constellation Catheter (K021232) and the Flower/PENTARAY High Density Mapping Catheter (K050217) based on comparison of the devices. The summation of the existing animal data, data from the IDE study (G940612) and the CONFIRM study (Narayan et al, 2012), along with the additional medical literature, support continued safety and effectiveness of the Constellation Catheter as it relates to expanding the current indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

Boston Scientific Corporation
Michelle Roeding
Principal, Regulatory Affairs
150 Baytech Drive
San Jose, CA 95134

Re: K140733

Trade/Device Name: Constellation® Multiple Electrode Recording and Pacing Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: MTD
Dated: March 25, 2014
Received: March 26, 2014

Dear Ms. Michelle Roeding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A stylized signature of Bram D. Zuckerman, M.D., written in black ink over a large, bold, outlined 'FDA' logo.

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K140733

Device Name

Constellation® Multiple Electrode Recording and Pacing Catheter

Indications for Use (Describe)

For use in right and left atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Date:

2014.04.28

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